

University of Groningen

## **Outcome and quality of life after endovascular abdominal aortic aneurysm repair in octogenarians**

Pol, Robert A.; Zeebregts, Clark J.; van Sterkenburg, Steven M. M.; Ferreira, Luis M.; Goktay, Yigit; Reijnen, Michel M. P. J.; Endurant Stent Graft Nat Selection

*Published in:*  
Journal of Vascular Surgery

*DOI:*  
[10.1016/j.jvs.2014.02.009](https://doi.org/10.1016/j.jvs.2014.02.009)

**IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.**

*Document Version*  
Publisher's PDF, also known as Version of record

*Publication date:*  
2014

[Link to publication in University of Groningen/UMCG research database](#)

### *Citation for published version (APA):*

Pol, R. A., Zeebregts, C. J., van Sterkenburg, S. M. M., Ferreira, L. M., Goktay, Y., Reijnen, M. M. P. J., & Endurant Stent Graft Nat Selection (2014). Outcome and quality of life after endovascular abdominal aortic aneurysm repair in octogenarians. *Journal of Vascular Surgery*, 60(2), 308-317.  
<https://doi.org/10.1016/j.jvs.2014.02.009>

### **Copyright**

Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

The publication may also be distributed here under the terms of Article 25fa of the Dutch Copyright Act, indicated by the "Taverne" license. More information can be found on the University of Groningen website: <https://www.rug.nl/library/open-access/self-archiving-pure/taverne-amendment>.

### **Take-down policy**

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Downloaded from the University of Groningen/UMCG research database (Pure): <http://www.rug.nl/research/portal>. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.

# Outcome and quality of life after endovascular abdominal aortic aneurysm repair in octogenarians

Robert A. Pol, MD, PhD,<sup>a</sup> Clark J. Zeebregts, MD, PhD,<sup>a</sup> Steven M. M. van Sterkenburg, MD,<sup>b</sup> Luis M. Ferreira, MD,<sup>c</sup> Yigit Goktay, MD,<sup>d</sup> and Michel M. P. J. Reijnen, MD, PhD,<sup>b</sup> for the Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE) Investigators, Groningen and Arnhem, The Netherlands; Buenos Aires, Argentina; and Alsancak, Turkey

**Objective:** This study determined outcome and quality of life (QOL) in octogenarians, compared with patients aged <80 years, 1 year after endovascular aortic aneurysm repair (EVAR).

**Methods:** From March 2009 until April 2011, 1263 patients in the Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE) registry with an abdominal aortic aneurysm were treated with EVAR using the Endurant endograft (Medtronic Cardiovascular, Santa Rosa, Calif). The patients were grouped according to those aged  $\geq 80$  years (290 [22.9%]) and those aged <80 years (973 [77.1%]) at the time of the procedure. QOL was assessed using composite EuroQoL 5-Dimensions Questionnaire (EQ-5D) index scores. Baseline, perioperative, and follow-up data were analyzed at 1 year.

**Results:** Octogenarians had poorer anatomic characteristics. The technical success rate was almost 99% for both cohorts, with no deaths. The duration of the implant procedure was significantly longer in the elderly patients ( $P = .002$ ), with significant differences in overall ( $P < .001$ ) and postprocedure ( $P < .001$ ) hospital stays in favor of the younger group. At 1 year, there was a significant difference in all-cause mortality ( $P = .002$ ) and in the number of major adverse events ( $P = .003$ ), including secondary rupture ( $P = .01$ ), to the detriment of octogenarians. There were no significant differences in conversion to open surgery or in overall secondary endovascular procedures. The octogenarians scored lower in their overall health care perception ( $P < .001$ ) but with no significant difference in the EQ-5D index. Compared with the group aged <80 years, they had still not completely recovered their QOL after 1 year ( $P = .01$ ).

**Conclusions:** Octogenarians are more difficult to treat by EVAR than younger patients due to poorer anatomic suitability and a higher incidence of complications. Recovery of QOL in octogenarians takes longer (>12 months) than expected. (J Vasc Surg 2014;60:308-17.)

Globally, there is a growing aging population in industrialized countries. In the United States, the cohort of octogenarians is increasing by as many as 160,000 persons per year.<sup>1</sup> Inevitably, this results in more elderly patients presenting with abdominal aortic aneurysms (AAAs) that need treatment. Because open AAA repair in this age group is associated with high morbidity and mortality rates, endovascular AAA repair (EVAR) is now considered the gold standard in these frail patients.<sup>2-7</sup> Although the feasibility of EVAR in octogenarians has been shown, possible effects on quality of life (QOL) must also be considered. Even when mortality rates are acceptable, decrements in issues

such as mobility and self-care can be of critical importance in these vulnerable patients.

The Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE) is a multicenter, noninterventive, nonrandomized, single-arm prospective study of the Endurant endograft device (Medtronic Cardiovascular, Santa Rosa, Calif).<sup>8</sup> In our previous report on the 30-day outcomes in patients aged  $\leq 80$  years compared with those >80 years, most parameters were similar between the two age groups but recovery of QOL measures appeared to occur sooner in those patients aged <80 years.<sup>9</sup> Although the 30-day outcome is a good measure for recovery after EVAR, the 1-year data, which we will describe in this report, will provide a more reliable representation and show whether full rehabilitation occurs in this group.

## METHODS

The study population included consecutive patients who were enrolled in the ENGAGE registry from 79 sites in Western, Central and Eastern Europe, Asia, South Africa, the Middle East, Latin America, and Canada. The patients were divided into two groups: those aged >80 years (290 [22.9%]) and those  $\leq 80$  years (973 [77.1%]) at the time of the procedure. The study is registered on [clinicaltrials.gov](http://clinicaltrials.gov) (NCT00870051). Information on study design, protocol-defined inclusion criteria, the Endurant stent graft system, data collection,

From the Division of Vascular Surgery, Department of Surgery, University Medical Center Groningen, University of Groningen, Groningen<sup>a</sup>; the Department of Surgery, Rijnstate Hospital, Arnhem<sup>b</sup>; the Department of Vascular Surgery of the Clinica La Sagrada Familia, Buenos Aires<sup>c</sup>; and the Department of Interventional Radiology, Dokuz Eylul University, Alsancak.<sup>d</sup>

Author conflict of interest: none.

Reprint requests: Robert A. Pol, MD, PhD, Division of Vascular Surgery, Department of Surgery, University Medical Center Groningen, PO Box 30001, 9700 RB Groningen, The Netherlands (e-mail: [pol.chirurgie@gmail.com](mailto:pol.chirurgie@gmail.com)).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214/\$36.00

Copyright © 2014 by the Society for Vascular Surgery.

<http://dx.doi.org/10.1016/j.jvs.2014.02.009>

monitoring and statistical methods has been published previously.<sup>8,9</sup>

Briefly, the preoperative risk assessment consisted of the American Society of Anesthesiologists Physical Status Classification and the Society for Vascular Surgery/International Society of Vascular Specialists (SVS/ISVS) score. Baseline comorbidities (hypertension, hyperlipidemia, diabetes, cancer, cardiac disease, tobacco use, renal insufficiency) and anatomic characteristics of the aneurysm (aneurysm diameter, length of nonaneurysmal neck, proximal and distal neck diameter, iliac artery diameters, and infrarenal neck angle) were tabulated.

Perioperative outcome data included the technical success of stent graft placement (defined by successful introduction of the delivery system and deployment of the device) and freedom from intraoperative death or type I/III endoleak. Successful delivery and deployment of the stent graft was defined as deployment of the Endurant Stent Graft System in the planned location, with no unintentional coverage of both internal iliac arteries or any visceral aortic branches, and with the removal of the delivery system. Successful implantation was defined as the absence of stent kinking or twisting, suprarenal bare stent fracture, or stent graft malfunction, including type I or IV endoleak.

Measures assessed after discharge included freedom from migration, graft occlusion, loss of structural integrity, endoleak, aneurysm expansion, major adverse device-related effects, and all-cause mortality.

QOL was assessed using the EuroQoL 5-Dimensions Questionnaire (EQ-5D) index score, a preference-based, generic instrument that measures QOL in three different ways.<sup>10,11</sup> The first part is a descriptive system profiling a respondent's health status in five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Reporting is on a scale of 1 (no problems) to 3 (extreme problems). The second measure is a 0 to 100 visual analog scale for self-rating of a patient's own health. The last measure, the "composite EQ-5D index," reflects the utility of the measured health profile from the perspective of the general population. Ratings took place at the first contact (baseline), at discharge, and at the 30-day and 1-year outpatient visits. Differences were measured at these assessments, comparing values between groups at each time point and within groups between baseline and each of the postoperative time points.

**Statistical analysis.** Differences between continuous variables were tested with the two-tailed Student *t*-test, except for hospital stay, procedural stay, and intensive care unit time, where the Wilcoxon rank sum test was applied. Normally distributed continuous variables are expressed as mean  $\pm$  standard deviation, and skewed variables are expressed as median and interquartile range. For categorical data, the Cochran-Mantel-Haenszel test was used. Two-tailed *P* values were used throughout, and significance was assumed when the *P* value was  $<.05$ . All statistical

analyses were performed with SAS 9.13 software (SAS Institute, Carey, NC).

## RESULTS

From March 2009 until April 2011, 1263 patients with infrarenal AAA were enrolled in the ENGAGE registry and treated with the Endurant endograft. Baseline characteristics are reported in Table I. The mean age was  $70.1 \pm 6.5$  years (range, 43-79 years) in patients  $<80$  years ( $n = 973$ ) and  $83.3 \pm 2.9$  years (range, 80-93 years) in patients aged  $\geq 80$  years ( $n = 290$ ). Sex distribution was skewed, with significantly more women in the octogenarian cohort ( $P = .039$ ). The frequency of tobacco use ( $P \leq .001$ ) and alcoholism ( $P = .006$ ) was higher in the group aged  $<80$  years. The overall incidence of cardiac disease was equally distributed, despite the presence of more arrhythmias in the octogenarian cohort ( $P = .004$ ). During the preoperative assessment, renal insufficiency ( $P = .01$ ) was more common in patients aged  $\geq 80$  years, whereas liver disease was more prevalent among younger patients ( $P = .01$ ). Octogenarians had significantly higher American Society of Anesthesiologists classifications ( $P < .001$ ) and SVS/ISVS scores ( $P < .001$ ).

**Anatomic characteristics.** The primary indication for endograft implant differed between the two groups. Octogenarians had larger aneurysms ( $61.9 \pm 11.3$  vs  $59.8 \pm 11.7$  mm), and the younger patients had more rapidly growing aneurysms (7.1% [69 of 973] vs 3.4% [10 of 290];  $P = .037$ ). Furthermore, octogenarians had significantly greater infrarenal neck angulation ( $33.2^\circ \pm 24.0^\circ$  vs  $29.5^\circ \pm 23.6^\circ$ ;  $P = .02$ ) and larger left iliac arteries ( $14.2 \pm 3.5$  vs  $13.6 \pm 3.5$  mm;  $P = .03$ ; Table II).

**Procedural data and hospital stay.** A preimplant adjunctive procedure (ie, coil embolization of internal iliac or inferior mesenteric artery) was more frequently required in the patients aged  $<80$  years ( $P = .04$ ; Table III). The type of anesthesia used was similar in both groups. The duration of implant procedure was significantly longer in the elderly group ( $106.7 \pm 42.5$  vs  $97.3 \pm 45.5$  minutes;  $P = .002$ ), and they also had slightly more blood loss ( $230.5 \pm 244.7$  vs  $201.4 \pm 211.8$  mL;  $P = .05$ ). There were no differences regarding arterial access entry site of the main body ( $P = .86$ ) or contralateral limb ( $P = .80$ ). However, there was a significant difference with respect to the number of distal graft extensions that were needed in favor of the younger patients ( $P < .001$ ).

Although the volume of contrast was similar in the two groups ( $P = .77$ ), the total fluoroscopy time was longer in the octogenarian cohort ( $22.0 \pm 13.6$  vs  $20.1 \pm 11.9$  minutes,  $P = .03$ ). The numbers of additional devices used or associated procedures performed during implant procedure were similar. The Endurant endograft was inserted and deployed with equal success in both groups ( $P = .606$ ). There were significant differences in overall ( $P < .001$ ) and postprocedure hospital stays ( $P < .001$ ) in favor of the younger group (Table III). Admittance to (35% vs 35%) and duration of intensive care unit stay (10.7 vs

**Table I.** Baseline and anatomic characteristics, risk factors, and comorbidity

Baseline characteristics <sup>a</sup>	Age <80 years (n = 973) <sup>b</sup>	Age ≥80 years (n = 290) <sup>b</sup>	P <sup>c</sup>
Age, years	70.1 ± 6.5	83.3 ± 2.9	NA
Sex			.04
Female	9.6 (93/973)	13.8 (40/290)	
Male	90.4 (880/973)	86.2 (250/290)	
Primary indication for implant			.04
Aneurysm diameter			
≥1.5× normal infrarenal aorta	3.7 (36/973)	1.7 (5/290)	
4–5 cm (≥0.5 cm increase in last 6 months)	7.1 (69/973)	3.4 (10/290)	
>5 cm	86.7 (844/973)	92.8 (269/290)	
Other	2.5 (24/973)	2.1 (6/290)	
Baseline symptoms			
None	83.4 (811/973)	85.5 (248/290)	.379
Abdominal pain	10.8 (105/973)	10.3 (30/290)	.829
Back pain	5.8 (56/973)	3.4 (10/290)	.121
Other	2.4 (23/973)	2.8 (8/290)	.703
Risk factors			
Tobacco use	56.5 (538/952)	24.6 (69/280)	<.001
Hypertension	75.9 (728/959)	73.9 (212/287)	.480
Hyperlipidemia	62.4 (574/920)	53.9 (145/269)	.012
Diabetes mellitus	19.9 (191/958)	15.7 (45/287)	.107
Cancer	19.9 (191/960)	22.3 (63/282)	.371
Alcoholism	4.0 (38/947)	0.7 (2/282)	.006
Cardiac disease	53.0 (515/972)	55.2 (160/290)	.512
Arrhythmia	14.4 (137/951)	21.5 (61/284)	.004
Pulmonary disease	25.1 (240/955)	25.4 (73/287)	.917
Renal insufficiency	13.9 (134/963)	20.1 (58/289)	.011
Carotid artery disease	10.8 (87/808)	11.3 (28/247)	.802
Cerebrovascular/neurologic disease	11.7 (114/972)	15.9 (46/290)	.063
Vascular disease	30.8 (299/972)	31.4 (91/290)	.842
Liver disease	2.9 (28/972)	0.3 (1/290)	.011
ASA classification			<.001
I	7.1 (69/972)	2.8 (8/290)	
II	43.6 (424/972)	35.5 (103/290)	
III	39.4 (383/972)	48.6 (141/290)	
IV	9.9 (96/972)	13.1 (38/290)	
SVS/ICVS Risk Level			<.001
0	0.1 (1/934)	0.0 (0/283)	
1	17.8 (166/934)	0.0 (0/283)	
2	66.4 (620/934)	0.0 (0/283)	
3	15.7 (147/934)	100.0 (283/283)	

ASA, American Society of Anesthesiologists; NA, not applicable; SVS/ISVS, Society for Vascular Surgery/International Society of Vascular Specialists.

<sup>a</sup>Continuous data are presented as mean ± standard deviation and categorical data as percentage (counts/n).

<sup>b</sup>n = number of intention-to-treat patients with nonmissing values. One patient can report more than one baseline symptom; hence, sum of all the counts can be more than the denominator.

<sup>c</sup>P values ≤.05 were considered statistically significant.

8 hours) was similar for both groups, as was the degree of initial implantation success. Endograft twisting ( $P = .01$ ) and perioperative type I endoleak (corrected;  $P < .001$ ) were more frequently observed in the octogenarian group. After correction of the endoleak during the same procedure, there was no longer a difference in this incidence of type I endoleak between the two groups ( $P = .618$ ). There was no difference regarding deviation from instructions for use (Table IV).

**Adverse events.** During follow-up, a significant discrepancy in major adverse events (MAEs) was evident between the two age groups. Whereas there was no difference in MAE incidence at 30 days,<sup>9</sup> a significant difference regarding all-cause mortality ( $P = .002$ ) and the number of MAEs ( $P = .003$ ) was observed after 1 year

(Fig 1). No single MAE category accounted for the difference; however, myocardial infarctions occurred in the octogenarian cohort at twice the frequency of younger patients. In addition, twice as many secondary endovascular procedures were necessary to correct type I/III endoleak in this group, although the difference did not reach significance. After 1 year, this resulted in a significant difference in the aneurysm rupture rate to the detriment of octogenarians (0% vs 0.7%;  $P = .01$ ). There was no significant difference regarding conversion to open surgery ( $P = .58$ ) or performance of overall secondary endovascular procedures ( $P = .34$ ; Table V; Fig 2).

**QOL assessments.** Table VI reports the QOL data between groups at each of the time points (intergroup differences) and within each group from the preoperative

**Table II.** Anatomic details

<i>Aneurysm measurements<sup>a</sup></i>	<i>Age &lt;80 years (n = 973)</i>	<i>Age ≥80 years (n = 290)</i>	<i>P<sup>b</sup></i>
Diameter			
Aneurysm, mm	59.8 ± 11.7	61.9 ± 11.3	.007
Proximal neck, mm	23.7 ± 3.6	23.8 ± 3.5	.912
Distal neck, mm	24.9 ± 4.1	24.9 ± 4.0	.844
Length of nonaneurysmal aortic neck, mm	26.9 ± 12.4	27.3 ± 12.3	.693
Distal diameter of nonaneurysmal neck of			
Right iliac artery, mm	14.0 ± 3.5	14.5 ± 3.7	.071
Left iliac artery, mm	13.6 ± 3.5	14.2 ± 3.5	.035
Infrarenal neck angle, °	29.5 ± 23.6	33.2 ± 24.0	.021

<sup>a</sup>Data are presented as mean ± standard deviation.

<sup>b</sup>P values ≤.05 were considered statistically significant.

**Table III.** Initial procedural data and hospital stay

<i>Variable<sup>a</sup></i>	<i>Age &lt;80 years (n = 926)</i>	<i>Age ≥80 years (n = 274)</i>	<i>P<sup>b</sup></i>
Preimplant adjunctive procedure	8.4 (82/973)	4.8 (14/290)	.042
Coil embolization of			
Hypogastric artery	4.6 (45/973)	3.1 (9/290)	.261
Inferior mesenteric artery	1.3 (13/973)	0.3 (1/290)	.157
Other procedure	2.7 (26/973)	1.4 (4/290)	.205
Type of anesthesia			
General	60.8 (592/973)	66.8 (193/289)	.068
Spinal	21.9 (213/973)	18.7 (54/289)	.241
Epidural	8.5 (83/973)	6.6 (19/289)	.284
Local	13.6 (132/973)	12.1 (35/289)	.522
Extension			<.001
Left femoral	14.3 (139/972)	11.4 (33/290)	
Left iliac	1.9 (18/972)	2.8 (8/290)	
Right femoral	18.2 (177/972)	25.2 (73/290)	
Right iliac	0.6 (6/972)	3.1 (9/290)	
Other	22.3 (217/972)	22.8 (66/290)	
NA	42.7 (415/972)	34.8 (101/290)	
Duration of implant procedure, min	97.3 ± 45.5	106.7 ± 42.5	.002
>1 SD compared with the mean, 45 min	93.5 (901/964)	98.3 (283/288)	.002
>2 SD compared with the mean, 45 min	52.2 (503/964)	64.9 (187/288)	.001
Estimated blood loss during procedure, mL	201.4 ± 211.8	230.5 ± 244.7	.051
Total fluoroscopic time, min	20.1 ± 11.9	22.0 ± 13.6	.026
Evaluation of Endurant <sup>c</sup>	99.0 (963/973)	99.3 (287/289)	.606
Endograft successfully delivered	99.4 (967/973)	99.7 (289/290)	.584
Endograft successfully deployed	99.4 (967/973)	99.7 (289/290)	.584
Endograft covered internal iliac arteries or any visceral aortic branches unintentionally	0.5 (5/971)	0.3 (1/289)	.714
Length of stay			
Overall hospital, <sup>d</sup> days	6.2 ± 6.6	7.6 ± 6.2	<.001
Procedural, <sup>e</sup> days	4.55 ± 4.91	5.75 ± 5.50	<.001
Intensive care unit, hours	10.7 ± 47.6	8.0 ± 17.0	.816
Intraoperative clinical success	97.5 (949/973)	97.9 (283/289)	.702
Technical success	99.0 (963/973)	99.3 (287/289)	.606
Freedom from intraoperative death	100.0 (973/973)	100.0 (290/290)	NA
Freedom from type I/III endoleak (uncorrected)	98.6 (954/968)	98.6 (285/289)	.938

NA, Not applicable.

<sup>a</sup>Continuous data are presented as mean ± standard deviation and categorical data as percentage (count/n).

<sup>b</sup>P values ≤.05 were considered statistically significant.

<sup>c</sup>Medtronic Cardiovascular, Santa Rosa, Calif.

<sup>d</sup>Calculated as the date of hospital discharge — date of hospital admission. When the two dates were the same, the overall hospital stay was considered to be 0.5 day.

<sup>e</sup>Calculated as the date of hospital discharge — date of initial procedure. When the two dates were the same, the procedural hospital stay was considered to be 0.5 day.

baseline assessment to discharge and 1 year (intragroup differences). At baseline, the two groups scored the same in most dimensions except for mobility ( $P = .03$ ) and self-care ( $P < .001$ ), which is to be expected. Although this

did not reach a significant intergroup difference, at the time of hospital discharge, both groups scored themselves lower in the dimensions of mobility, self-care, usual activity, and pain/discomfort. Only the dimension of usual activity was

**Table IV.** Initial endograft outcome

Event	Age <80 years (n = 968), % (count/n)	Age ≥80 years (n = 289), % (count/n)	P <sup>a</sup>
Endograft kinking	0.9 (9/966)	1.4 (4/288)	.502
Endograft twisting	0.2 (2/965)	1.4 (4/288)	.011
Endograft wire fracture	0.0 (0/966)	0.0 (0/288)	NA
Suprarenal bare stent fracture	0.0 (0/966)	0.0 (0/288)	NA
Additional endograft malfunction(s)	0.3 (3/968)	0.3 (1/289)	.924
Endoleak (corrected)	7.7 (75/968)	13.8 (40/289)	.002
Type I	4.5 (44/968)	11.4 (33/289)	<.001
Type II	1.9 (18/968)	2.1 (6/289)	.819
Type III	1.2 (12/968)	0.3 (1/289)	.188
Type IV	0.1 (1/968)	0.0 (0/289)	.585
Undetermined	0.1 (1/968)	0.3 (1/289)	.364
Endoleak (uncorrected)	15.2 (147/968)	19.0 (55/289)	.118
Type I	1.0 (10/968)	1.4 (4/289)	.618
Type II	11.7 (113/968)	15.2 (44/289)	.110
Type III	0.4 (4/968)	0.0 (0/289)	.274
Type IV	1.4 (14/968)	2.8 (8/289)	.133
Undetermined	0.9 (9/968)	0.0 (0/289)	.100
Treated outside IFU	18.2 (117/973)	16.9 (49/290)	.614

IFU, Instructions for use; NA, not applicable.

<sup>a</sup>P values ≤.05 were considered statistically significant.

found to be significantly different at discharge. After 1 year, the octogenarian cohort, compared with the patients aged <80 years, still experienced problems in mobility ( $P < .001$ ), self-care ( $P < .001$ ), usual activity ( $P < .001$ ), and in perception of pain and discomfort ( $P = .001$ ). A small intragroup improvement was noted regarding mobility, pain/discomfort, and anxiety/depression in the octogenarian cohort. Improvements in the younger cohort were seen in the dimensions self-care, pain/discomfort, and anxiety/depression. At 1 year, octogenarians scored lower in their overall health care perception ( $P < .001$ ) but did not have a significant difference in EQ-5D index. However, unlike the group aged <80 years, complete recovery was not observed in the octogenarian group after 1 year ( $P = .014$ ). This difference was not visible in the period between discharge and the 1-year follow-up ( $P = .160$ ); thus, the impairment must have occurred during hospital stay/surgery.

## DISCUSSION

The technical success rates of EVAR in octogenarians in initial endograft placement and outcome are high (99.3%); however, the procedure has important implications with respect to overall mortality, aneurysm rupture, and QOL. The higher number of additional procedures (preimplant, graft extensions, and endoleak corrections), the prolonged duration of surgery, increased blood loss, and extended hospital stay should also be taken into account. Although a certain risk may be justifiable, even in as vulnerable a group as octogenarians, this study shows that EVAR also has implications for recovery and preservation of QOL. Marked improvements occur in a number of domains, but recovery is still not complete in mobility, self-care, and usual activities in octogenarians after 1 year,

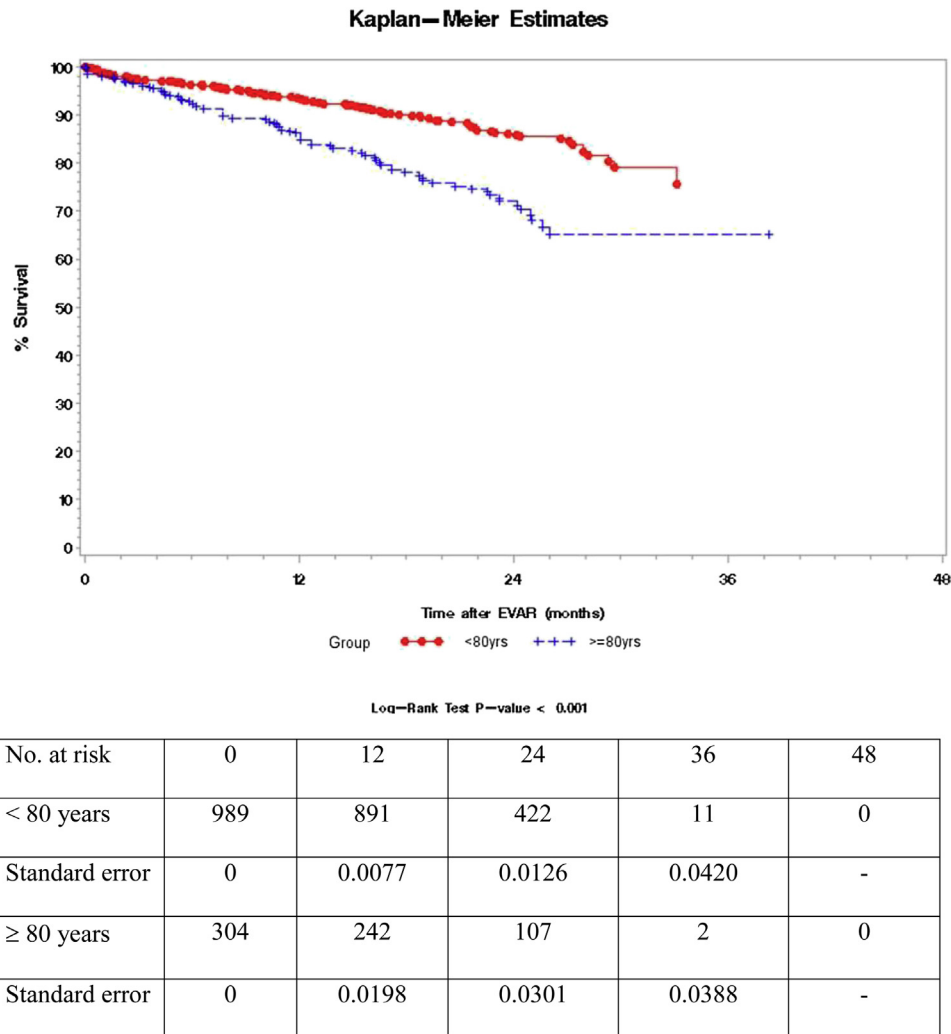
suggesting that the effect of EVAR is greater in octogenarians than previously thought.

As noted in our previous report on 30-day outcome, octogenarians have a similar initial endograft outcome in overall terms, despite the aberrant anatomy, compared with the younger cohort. The anatomic differences did not lead to a lower technical success rate or an increased need for early secondary interventions ≤30 days, and this was unchanged after 1 year. Nevertheless, the significant difference in aneurysm rupture rates is, at the very least, an alarming and troubling finding. Given that the overall distribution of comorbidities is similar in both groups, except in some cardiovascular risk factors, the differences in anatomic characteristics described in Table II may be determinative. Together with the larger aneurysm diameters, this has to be considered a risk factor for late rupture.

In general, practitioners are reluctant to offer aneurysm surgery to elderly patients because the risk of aneurysm rupture is sometimes difficult to balance against the surgical risk. This must be weighed against the natural, and often limited, life expectancy of octogenarians. Previous publications, including those from our clinic, have shown that EVAR is and remains the treatment of choice in octogenarians because the short-term benefits have been especially substantial.<sup>3-6,12-16</sup> But despite these advantages and the high procedural success in this specific patient group, the periprocedural and postprocedural morbidity and mortality are higher than that of their younger counterparts. This difference is even greater after emergency surgery and open AAA repair.<sup>6,17</sup>

Our series found a significant difference in all-cause mortality at 1 year to the detriment of the octogenarians. This is mainly determined by the higher rate of myocardial infarctions (3.2%) and secondary aneurysm ruptures in the





**Fig 1.** Probability of survival according to the Kaplan-Meier method after endovascular aneurysm repair (EVAR) in patients aged  $\geq 80$  years (blue line) compared with patients aged  $< 80$  years (red line).

elderly patients. Because all patients in the octogenarian group were classified SVS/ISVS 3, the difference in fatal cardiac events is not a surprising result and appears independent of surgery. However, a higher incidence of aneurysm rupture after EVAR is an outcome more commonly reported in the literature. A large systematic review and meta-analysis reported a significantly higher rate of aortic rupture after EVAR compared with open repair (odds ratio, 5.94;  $P < .001$ ).<sup>18</sup> In addition, the deviant and challenging anatomy in elderly patients carries a higher risk of type I endoleak, with a subsequent increased risk of late rupture.<sup>19,20</sup> In the present study, we found a higher incidence of perioperative type I endoleak in the octogenarians. This difference disappeared after perioperative correction; thus, type I endoleak did not seem to be attributed to the higher incidence of aneurysm rupture in the octogenarians. The difference in late ruptures cannot be ignored but should be placed into perspective, because a difference of the two

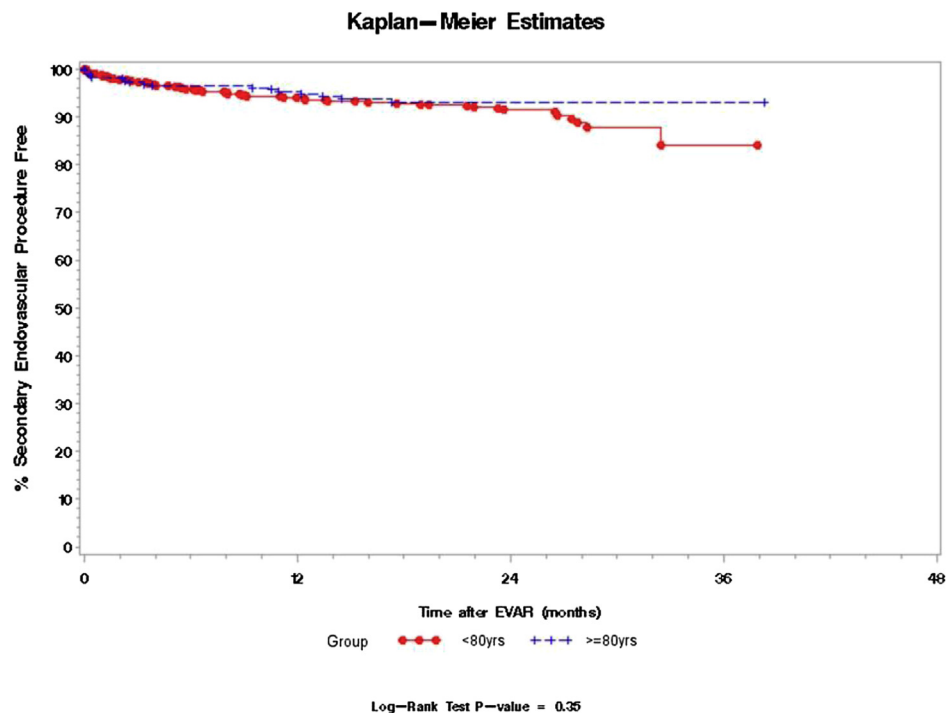
events is negligible in daily practice and is presumably superior to no repair. EVAR offers an important benefit over open repair in elderly patients, with significantly less major systemic morbidity than open repair.

Interestingly, the perioperative death rate of both procedures in this age category is virtually the same.<sup>5</sup> This is a striking difference from studies that describe EVAR and open repair results in patients of all ages, in which EVAR demonstrates a lower 30-day mortality.<sup>21</sup> It indicates that the outcome of aneurysm surgery in this vulnerable group is independent of the type of surgery.

The length of recovery to baseline functional level and QOL attains particular importance in octogenarians with their limited life expectancy. We had expected, from the 30-day data, that recovery would have occurred much sooner. Although QOL is decreased after AAA repair, EVAR would logically provide an advantage over open surgery. The literature, however, demonstrates precisely the

**Table V.** Major adverse events (MAEs) within 1 year

Event	Age <80 years (n = 963), % (count/n)	Age ≥80 years (n = 283), % (count/n)	P <sup>a</sup>
All-cause mortality	6.2 (60/963)	11.7 (33/283)	.002
≥1 MAEs	9.9 (95/963)	16.3 (46/283)	.003
Bowel ischemia	0.2 (2/963)	0.4 (1/283)	
Myocardial infarction	1.7 (16/963)	3.2 (9/283)	
Paraplegia	0.0 (0/963)	0.0 (0/283)	
Renal failure	1.0 (10/963)	1.4 (4/283)	
Respiratory failure	0.1 (1/963)	0.0 (0/283)	
Stroke	0.5 (5/963)	0.4 (1/283)	
Aneurysm-related			
Conversion to open surgery	0.6 (6/973)	0.3 (1/290)	.58
Aneurysm rupture	0.0 (0/973)	0.7 (2/290)	.01
Secondary endovascular procedure	6.0 (58/973)	4.5 (13/290)	.34
Secondary endovascular procedure to correct type I/III endoleak	1.1 (11/973)	2.4 (7/290)	.11

<sup>a</sup>P values ≤.05 were considered statistically significant.

No. at risk	0	12	24	36	48
< 80 years	973	828	386	9	0
Standard error	0	0.0077	0.0100	0.0392	-
≥ 80 years	290	226	101	3	0
Standard error	0	0.0129	0.0166	0.0166	-

**Fig 2.** Probability of intervention-free survival according to the Kaplan-Meier method after endovascular aneurysm repair (EVAR) in patients aged ≥80 years (blue line) compared with patients aged <80 years (red line).



**Table VI.** Outcome of activities of daily living and quality of life (QOL)

Variable <sup>a</sup>	Age <80 years (n = 973)	Age ≥80 years (n = 290)	P <sup>b</sup>
Baseline			
Mobility			.033
1 (no problem)	71.1 (663/932)	63.8 (176/276)	
2 (some problems)	28.1 (262/932)	35.9 (99/276)	
3 (extreme problems)	0.8 (7/932)	0.4 (1/276)	
Self-care			<.001
1 (no problem)	92.5 (862/932)	84.1 (232/276)	
2 (some problems)	6.4 (60/932)	14.1 (39/276)	
3 (extreme problems)	1.1 (10/932)	1.8 (5/276)	
Usual activities			.094
1 (no problem)	81.7 (761/932)	76.4 (211/276)	
2 (some problems)	16.0 (149/932)	21.0 (58/276)	
3 (extreme problems)	2.4 (22/932)	2.5 (7/276)	
Pain/discomfort			.964
1 (no problem)	65.1 (607/932)	64.5 (178/276)	
2 (some problems)	31.9 (297/932)	33.0 (91/276)	
3 (extreme problems)	3.0 (28/932)	2.5 (7/276)	
Anxiety/depression			.212
1 (no problem)	71.6 (667/932)	75.4 (208/276)	
2 (some problems)	25.2 (235/932)	22.1 (61/276)	
3 (extreme problems)	3.2 (30/932)	2.5 (7/276)	
Your own health state today (0, bad; 100, excellent)	73.1 ± 16.5	73.0 ± 16.2	.909
Median (IQR)	75 (64-85)	75 (63-80)	
EQ-5D Index	0.86 ± 0.17	0.85 ± 0.17	.372
Median (IQR)	0.84 (0.81-1.00)	0.84 (0.79-1.00)	
At discharge			
Mobility			.068
1 (no problem)	56.4 (457/811)	50.2 (118/235)	
2 (some problems)	42.2 (342/811)	47.2 (111/235)	
3 (extreme problems)	1.5 (12/811)	2.6 (6/235)	
Self-care			.092
1 (no problem)	76.3 (618/810)	72.3 (170/235)	
2 (some problems)	22.3 (181/810)	24.3 (57/235)	
3 (extreme problems)	1.4 (11/810)	3.4 (8/235)	
Usual activities			.043
1 (no problem)	62.1 (504/811)	53.6 (126/235)	
2 (some problems)	31.7 (257/811)	39.6 (93/235)	
3 (extreme problems)	6.2 (50/811)	6.8 (16/235)	
Pain/discomfort			.527
1 (no problem)	46.3 (375/810)	43.8 (103/235)	
2 (some problems)	51.2 (415/810)	53.6 (126/235)	
3 (extreme problems)	2.5 (20/810)	2.6 (6/235)	
Anxiety/depression			.863
1 (no problem)	81.2 (658/810)	81.3 (191/235)	
2 (some problems)	17.7 (143/810)	17.0 (40/235)	
3 (extreme problems)	1.1 (9/810)	1.7 (4/235)	
Your own health state today (0, bad; 100, excellent)	72.3 ± 15.8	70.1 ± 16.7	.076
Median (IQR)	74 (60-84)	70 (60-80)	
EQ-5D Index	0.81 ± 0.18	0.79 ± 0.18	.085
Median (IQR)	0.83 (0.75-1.00)	0.81 (0.71-1.00)	
Change in EQ-5D from baseline to discharge	-0.05 ± 0.17	-0.06 ± 0.17	.492
Median (IQR)	0 (-0.16 to 0)	0 (-0.16 to 0)	
After 12 months			
Mobility			<.001
1 (no problem)	70.9 (524/739)	57.9 (114/197)	
2 (some problems)	28.3 (209/739)	41.6 (82/197)	
3 (extreme problems)	0.8 (6/739)	0.5 (1/197)	
Self-care			<.001
1 (no problem)	93.9 (694/739)	81.2 (160/197)	
2 (some problems)	5.4 (40/739)	16.2 (32/197)	
3 (extreme problems)	0.7 (5/739)	2.5 (5/197)	
Usual activities			<.001
1 (no problem)	81.5 (602/739)	68.5 (135/197)	
2 (some problems)	16.2 (120/739)	29.4 (58/197)	
3 (extreme problems)	2.3 (17/739)	2.0 (4/197)	

(Continued on next page)

Table VI. Continued.

Variable <sup>a</sup>	Age <80 years (n = 973)	Age ≥80 years (n = 290)	P <sup>b</sup>
Pain/discomfort			.001
1 (no problem)	75.9 (561/739)	67.0 (132/197)	
2 (some problems)	22.6 (167/739)	27.4 (54/197)	
3 (extreme problems)	1.5 (11/739)	5.6 (11/197)	
Anxiety/depression			.342
1 (no problem)	84.6 (625/739)	82.2 (162/197)	
2 (some problems)	14.2 (105/739)	15.7 (31/197)	
3 (extreme problems)	1.2 (9/739)	2.0 (4/197)	
Your own health state today (0, bad; 100, excellent)	78.8 ± 15.5	74.1 ± 17.1	<.001
Median (IQR)	80 (70-90)	75 (62.5-90)	
EQ-5D Index	0.90 ± 0.15	0.84 ± 0.19	.083
Median (IQR)	1.00 (0.83-1.00)	0.85 (0.78-1.00)	
Change in EQ-5D from baseline to 12 months	0.03 ± 0.17	-0.00 ± 0.17	.014
Median (IQR)	0 (0-0.16)	0 (-0.06 to 0.06)	
Change in EQ-5D from discharge to 12 months	0.07 ± 0.18	0.05 ± 0.19	.160
Median (IQR)	0.04 (0-0.17)	0.04 (0-0.17)	

EQ-5D, EuroQoL 5-Dimensions Questionnaire; IQR, interquartile range.

<sup>a</sup>Categorical data are presented as percentage (count/n) and continuous data as mean ± standard deviation, unless stated otherwise.<sup>b</sup>P values ≤.05 were considered statistically significant.

opposite, with higher QOL scores after 6 months of follow-up in favor of open repair.<sup>22,23</sup> In addition, a recent study showed that the recovery time after AAA surgery for all ages is at least 12 months<sup>24</sup>; therefore, that recovery time would be even more prolonged for octogenarians seems logical.

Changes in QOL depend strongly on preoperative information disclosure and patient expectations. Providing proper information goes beyond procedure-related mortality and morbidity but should also provide the patient with more awareness on preservation and loss in QOL after surgery. The current results show that recovery in QOL and the domains of “mobility” and “usual activity” is delayed longer than expected. Providing more awareness is probably more important than previously thought and may even contribute to a faster recovery.

This study has some limitations. Despite the limited inclusion and exclusion criteria of the registry, all patients included were suitable for AAA repair with an endovascular endograft. In addition, we describe the outcomes after elective surgery. Although the results in QOL are likely to be the same after emergency surgery, there is a known difference in the occurrence of complications. Also, there is a known interplay of advanced age and technical challenging anatomy in the literature. Even though the reported differences are undoubtedly age-related, they may be slightly distorted by differences in anatomy. Various patients were lost to follow-up, which this could have led to some form of selection bias, especially for assessing overall health and QOL.

The strength of our study of these 1263 patients is the precision of estimates of the incidence of adverse effects. The weakness of such a large cohort is that statistically significant differences may be found that have little clinical significance; for example, the small differences in blood loss, duration of implant procedure, or fluoroscopic time

have no significance in everyday practice. We are aware of this problem, but given the consequences of, for instance, AAA rupture, considered it important enough to mention. The greater rate of mortality at 1 year can be at least partly attributed to the older age of the group. To suggest or demonstrate that it is related to EVAR, one would need to compare it to population-based data. We left that out of consideration in the current report.

## CONCLUSIONS

EVAR can safely be performed in octogenarians, albeit with aberrant anatomy requiring more femoral or iliac extensions and with a higher incidence of complications, including rupture. The effect on QOL and recovery to baseline functioning, however, is greater in octogenarians and seems to last at least >1 year.

## AUTHOR CONTRIBUTIONS

Conception and design: RP, CZ, MR

Analysis and interpretation: RP

Data collection: RP

Writing the article: RP, CZ, MR

Critical revision of the article: RP, CZ, SS, LF, YG, MR

Final approval of the article: RP, CZ, SS, LF, YG, MR

Statistical analysis: RP

Obtained funding: Not applicable

Overall responsibility: RP

## REFERENCES

1. U.S. Census Bureau. Available at: [www.census.gov](http://www.census.gov). Accessed May 8, 2007.
2. Henebiens M, Vahl A, Koelemay MJ. Elective surgery of abdominal aortic aneurysms in octogenarians: a systematic review. *J Vasc Surg* 2008;47:676-81.
3. Lange C, Leurs LJ, Buth J, Myhre HO; on behalf of the EUROSTAR collaborators. Endovascular repair of abdominal aortic aneurysm in

- octogenarians: an analysis on EUROSTAR data. *J Vasc Surg* 2005;42:624-30.
4. Ballotta E, Da Giau G, Bridda A, Gruppo M, Pauletto A, Martella B. Open abdominal aortic aneurysm repair in octogenarians before and after the adoption of endovascular grafting procedures. *J Vasc Surg* 2008;47:23-30.
5. Ballotta E, Da Giau G, Gruppo M, Mazzalai F, Spirch S, Terranova O. Elective abdominal aortic aneurysm repair in the very elderly: a systematic review. *Minerva Med* 2009;100:95-103.
6. Scheer MLJ, Pol RA, Haveman JW, Tielliu IFJ, Verhoeven ELG, van den Dungen JJAM, et al. Effectiveness of treatment for octogenarians with acute abdominal aortic aneurysm. *J Vasc Surg* 2011;53:918-25.
7. Biancari F, Mazziotti MA, Paone R, Laukontaus S, Venermo M, Lepäntalo M. Outcome after open repair of ruptured abdominal aortic aneurysm in patients >80 years old: a systematic review and meta-analysis. *World J Surg* 2011;35:1662-70.
8. Böckler D, Fitridge R, Wolf Y, Hayes P, Silveira PG, Numan F, et al. ENGAGE Investigators. Rationale and design of the Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE): interim analysis at 30 days of the first 180 patients enrolled. *J Cardiovasc Surg* 2010;51:481-91.
9. Pol RA, Zeebregts CJ, van Sterkenburg SM, Reijnen MM. for the ENGAGE Investigators. Thirty-day outcome and quality of life after endovascular abdominal aortic aneurysm repair in octogenarians based on the Endurant Stent Graft Natural Selection Global Post-market Registry (ENGAGE). *J Vasc Surg* 2012;56:27-35.
10. Ravens-Sieberer U, Wille N, Badia X, Bonsel G, Burström K, Cavrini G, et al. Feasibility, reliability, and validity of the EQ-5D-Y: results from a multinational study. *Qual Life Res* 2010;19:887-97.
11. Cavrini G, Broccoli S, Puccini A, Zoli M. EQ-5D as a predictor of mortality and hospitalization in elderly people. *Qual Life Res* 2012;21:269-80.
12. Sicard GA, Rubin BG, Sanchez LA, Keller CA, Flye MW, Picus D, et al. Endoluminal graft repair for abdominal aortic aneurysms in high-risk patients and Octogenarians. Is it better than open repair? *Ann Vasc Surg* 2001;234:427-37.
13. Paolini D, Chahwan S, Wojnarowski B, Pigott JP, Laporte F, Comerota J. Elective endovascular and open repair of abdominal aortic aneurysms in octogenarians. *J Vasc Surg* 2008;47:924-7.
14. Tsilimparis N, Perez S, Dayama A, Ricotta JJ 2nd. Age-stratified results from 20,095 aortoiliac aneurysm repairs: should we approach octogenarians and nonagenarians differently? *J Am Coll Surg* 2012;215:690-701.
15. Geisbüsch P, Katzen BT, Tsoukas AI, Arango D, Peña CS, Benenati JF. Endovascular repair of infrarenal aortic aneurysms in octogenarians and nonagenarians. *J Vasc Surg* 2011;54:1605-13.
16. Prener SB, Turnbull IC, Malik R, Salloum A, Ellozy SH, Vouyouka AG, et al. Outcome of elective endovascular abdominal aortic aneurysm repair in octogenarians and nonagenarians. *J Vasc Surg* 2010;51:1354-9.
17. Opfermann P, von Allmen R, Diehm N, Widmer MK, Schmidli J, Dick F. Repair of ruptured abdominal aortic aneurysm in octogenarians. *Eur J Vasc Endovasc Surg* 2011;42:475-83.
18. Stather PW, Sidloff D, Dattani N, Choke E, Bown MJ, Sayers RD. Systematic review and meta-analysis of the early and late outcomes of open and endovascular repair of abdominal aortic aneurysm. *Br J Surg* 2013;100:863-72.
19. Aburahma AF, Campbell JE, Mousa AY, Hass SM, Stone PA, Jain A, et al. Clinical outcomes for hostile versus favorable aortic neck anatomy in endovascular aortic aneurysm repair using modular devices. *J Vasc Surg* 2011;54:13-21.
20. Stather PW, Sayers RD, Cheah A, Wild JB, Bown MJ, Choke E. Outcomes of endovascular aneurysm repair in patients with hostile neck anatomy. *Eur J Vasc Endovasc Surg* 2012;44:556-61.
21. Lovegrove RE, Javid M, Magee TR, Galland RB. A meta-analysis of 21178 patients undergoing open or endovascular repair of abdominal aortic aneurysm. *Br J Surg* 2008;95:677-84.
22. Prinssen M, Buskens E, Blankensteijn JD. DREAM trial participants. Quality of life endovascular and open AAA repair. Results of a randomized trial. *Eur J Vasc Endovasc Surg* 2004;27:121-7.
23. Aljabri B, Al Wahaibi K, Abner D, Mackenzie KS, Corriveau MM, Obrand DI, et al. Patient-reported quality of life after abdominal aortic aneurysm surgery: a prospective comparison of endovascular and open repair. *J Vasc Surg* 2006;44:1182-7.
24. Coughlin PA, Jackson D, White AD, Bailey MA, Farrow C, Scott DJ, et al. Meta-analysis of prospective trials determining the short- and mid-term effect of elective open and endovascular repair of abdominal aortic aneurysms on quality of life. *Br J Surg* 2013;100:448-55.

Submitted Nov 28, 2013; accepted Feb 11, 2014.